

BIOLOGICS LICENSE APPLICATION

Division 2, Chapter 4, California Health and Safety Code

INSTRUCTIONS: Complete this application and personnel report and return with required fee. Send to:

California Department of Public Health
Laboratory Field Services
320 West 4th Street, Suite 890
Los Angeles, CA 90013

Make check payable to:
California Department of Public Health

1. Check type of facility to which license will apply <input type="checkbox"/> Blood bank <input type="checkbox"/> Transfusion service <input type="checkbox"/> Other (specify) _____	2. If new facility, give date of opening
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3. Name of facility _____

4. Address (number, street)	City	ZIP code
Telephone number ()	Fax number ()	E-mail address

5. If this application is being filed because of a change, indicate change <input type="checkbox"/> Address <input type="checkbox"/> Owner <input type="checkbox"/> Medical director or person in charge of production	Effective date of change
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6. Check type of ownership
 Individual Partnership Corporation Other (specify city, county, district, etc.) _____

7. Exact name of owner _____

a. Give name and address of (1) individual, if individual applying; (2) one member of partnership, if partnership; (3) president or secretary, if corporation or other similar type of organization; or (4) hospital administrator, if facility owned and operated by hospital.

Name	Address (number, street)	City	ZIP code
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b. List all other members of partnership or members of corporation board of directors (use supplementary sheet if necessary).

8. Person(s) in charge of biologics production (medical director, if blood bank)

Name	Address (Number, Street)	City, State, ZIP Code	Hours Per Week To Be Spent In This Facility

9. Products—List biologic(s) to be produced under this license

10. **FOR NEW FACILITIES**, attach description of facilities including (a) a description of the building with floor plan and (b) a list of equipment and apparatus used in production of biologics.

11. Complete enclosed personnel report and include with application.

12. a. List all off-site blood collection centers operating under this license.

Name	Address (Number, Street)	City, State, ZIP Code	Telephone Number

b. Mobile units Yes No If yes, please indicate number of mobile units _____

c. Off-site storage, processing, and/or distribution locations? Yes No

If yes, please indicate address and telephone number of each location.

Address (Number, Street)	City, State, ZIP Code	Telephone Number

I declare under penalty of perjury that the foregoing statements are true and correct; that I have read Division 2, Chapter 4 of the California Health and Safety Code; and Chapter 2, Subchapter 1, Group 1 of Title 17, California Code of Regulations; and that if a license is granted upon this application, the facility regulated by it will be conducted in accordance with the provisions of the aforementioned laws and regulations. I also certify that my connection with the above facility is bona fide, as shown, and that no subterfuge or mental reservation exists in connection with this application.

13. Certification of person named under 7.a.

Signature	Date
Printed name	

14. Certification of person named under 8.

Signature	Date
Printed name	

Facilities Licensed for the
Production of Blood and
Blood Components (Biologics)

Subject: CURRENT FEE SCHEDULE

The fee schedule for both initial application and renewal of Biologics Licenses is determined by Section 1616.5 of the California Health and Safety Code (CHSC), and adjusted by the annual fee increase provisions of CHSC 100450, subdivision (a).

The fees for a Biologics License is found on the internet at:

<http://www.cdph.ca.gov/programs/lfs/Documents/A-License-FeeSchedules.pdf>

PLEASE BE ADVISED THAT THERE IS NO LONGER AN EXEMPTION FROM PAYMENT OF FEES BY ANY FACILITY.

CHSC 1616. Fees: expiration; renewal.

- (a) Each application for license or license renewal under this chapter shall be accompanied by a fee determined by regulations and in an amount sufficient to cover the costs administering this chapter but not to exceed those costs, as specified pursuant to Section 1616.5.

- (c) Each license issued under this chapter shall expire 12 months from the date of its issuance. APPLICATION FOR RENEWAL OF LICENSE ACCOMPANIED BY THE FEE SHALL BE FIELD WITH THE DEPARTMENT EACH YEAR NOT LESS THAN 10 DAYS PRIOR TO THE EXPIRATION EACH YEAR. FAILURE TO MAKE A TIMELY RENEWAL SHALL RESULT IN EXPIRATION OF THE LICENSE.

Please feel free to call Robert Hunter at (213) 620-6574 in our Los Angeles office if you have questions.